DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

FILE COPY

August 30, 2005

Minnie Baylor-Henry
Vice-President, Medical and Regulatory Affairs
Ortho-McNeil Pharmaceutical, Inc.
Camp Hill Road
Ft. Washington, PA 19034

Dear Ms. Baylor-Henry:

Your petition requesting the Food and Drug Administration to require that standard bioequivalence criteria be applied separately to oxybutynin and its active metabolite, desethyloxbutynin, to ensure that approved generic versions of DITROPAN XL are both equivalent and clinicaly equivalent to the innovator product, was received by this office on 08/29/2005. It was assigned docket number 2005P-0352/CP 1 and it was filed on 08/30/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no Way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0352

ACK!